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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,716	03/30/2001	David A. Edwards	2685.1003-008	7248

21005 7590 04/23/2003

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/822,716	EDWARDS ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Extension of Time. The Amendment A, and the Information Disclosure Statement, all received by the Office January 31, 2003.

Information Disclosure Statement

The examiner has included the signed Information Disclosure Statement in this office action. Although all of the references are not present in the instant application, they are considered based on Applicant's recognition that they were considered in the parent application, serial number 09/383,054.

Double Patenting

After considering Applicant's arguments drawn to the double patenting rejections, these rejections are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-7, 11-17, 21-26, 28, 49, and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,043,214 to Jensen *et al.*.

Jensen *et al.* disclose a process for producing a therapeutic powder formulation . More specifically, Jensen *et al.* teach a dry powder composition comprising insulin or an analogue or derivative thereof, an enhancer, and zinc (column 2, lines 46-48). Jensen *et al.* also teach that administration of insulin via the pulmonary route an be accomplished by either an aqueous solution or a powder preparation (column 1, lines 51-55). Jensen *et al.* also teach that the enhancer can be a phospholipid, such as lysophosphatidycoline (column 3, lines 1-7). Jensen *et al.* teach that in a particular embodiment of the present invention the solution (which is later dried to form a dry powder) further comprises zinc, preferably in an amount corresponding to between 2 and 12 Zn atoms per insulin hexamer (column 3, lines 41-45). The reference also teaches that amino acids such as Leucine, Alanine and Valine (column 7, claims 23). Jensen *et al.* also teach that the size of the particles is between 1-5 microns (column 4, line 47). Lastly, Jensen *et al.* teach that the powder formulation obtained in their disclosure may optionally be combined with a carrier or excipient generally accepted as suitable for pulmonary administration (column 4, lines 9-12).

Response to Arguments

Applicant's arguments have been considered but are not found to be persuasive. Applicant argues that Jensen describes a process of producing a "dry" powder formulation comprising precipitation, wherein the precipitation is performed essentially without evaporating of the solution, and then removing the solution. Applicant further argues that Jensen does not does not teach spray drying. These arguments are not found persuasive. Applicant's current

claims are drawn to a composition and a method of using that composition, not a process of making the composition. All that is required to anticipate claim 1 is a method of delivery to the pulmonary system of a powder comprising a multivalent cation, an active, and a carrier. Likewise, all that is required to anticipate claim 30 is a composition comprising an active agent, a carrier and a multivalent cation. Jensen clearly meets the limitations of these claims. In the method of using claims, it is unclear what criticality the process of making the powder has on the success of the use of the powder. Jensen teaches a composition comprising the same components, and the use of that composition in the same manner, therefore anticipating the above claims. The limitation drawn to spray drying has no patentable weight in a claim drawn to the method of using the composition. The burden is shifted to Applicant to show any criticality the spray drying limitation has on the use of the composition. Likewise, the limitation drawn to spray drying has no criticality on a claim drawn to a composition. According to the MPEP section 2113, "even though product by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production, If the product in the product-by-process claim is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed.Cir. 1985). Applicant is reminded that any experimental data provided to show criticality must be in declaration form, and should be commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen *et al.*, as discussed above, and in view of the following comments.

Jensen *et al.* are discussed above as teaching a formulation for pulmonary use comprising insulin, or an analogue or derivative thereof, an enhancer, which can be phosphatidycholine, and zinc. Jensen *et al.* do not teach the tap density of the formulation, as claimed in the instant claims. The burden is shifted to applicant to show that the composition described by Jensen *et al.* does not contain the same properties as the instantly claimed formulation. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Additionally, Jensen *et al.* do not teach the inclusion of a carboxylic acid. However, the reference does teach that the pH is adjusted. Additionally, carboxylic acids, such as citric acid, are well known pH adjusters, in both the cosmetic and pharmaceutical arts. [See the attached

excerpt from the International Cosmetuic Ingredient Dictionary and Handbook- which lists citric acid as a well known pH adjuster.] It is the position of the examiner that citric acid is a well known component in pharmaceutical formulations. Additionally, it is known to perform a function which is specifically required by the teachings of Jensen, pH adjustment. Therefore, one of ordinary skill in the art would have bee motivated to use citric acid in the formulation of Jensen, to perform the pH adjusting function. The expected result would be a successful formulation for the pulmonary delivery of insulin. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments have been fully considered but are not found to be persuasive. The arguments are discussed above, and no further response is deemed necessary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
April 18, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600